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Oncology Section EDGE Task Force on Urogenital Cancer: A Systematic Review of Clinical Measures for Incontinence

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Abstract

Background—Compared to the general population, women and men with urogenital and colorectal cancer experience higher rates of urinary and fecal incontinence. Although a variety of measures exist to assess these areas, currently, there are no guidelines recommending which outcomes rehabilitation professionals should administer to examine these impairments in those with cancer.

Purpose—To identify outcome measures for assessing urinary and fecal incontinence and evaluate their psychometric data and applicability to the cancer population.

Methods—Multiple electronic databases (CINAHL, Medline, PsycInfo) were reviewed using specific search terms to locate articles that identify outcome measures assessing urinary and fecal incontinence. As part of a larger effort to identify outcome measures for both incontinence and sexual dysfunction, 1118 articles were initially identified, 228 articles were reviewed, and 37 outcome measures were selected for analysis, 13 of which were related to urinary and fecal incontinence. Each incontinence outcome measure was independently reviewed and rated by two reviewers using the Cancer EDGE Task Force Outcome Measure Rating Form. Any discrepancies between reviewers were discussed and an overall recommendation for each outcome measure was made using the 4-point Cancer EDGE Task Force Rating Scale.

Results—The Task Force was able to highly recommend 1 measure addressing urinary incontinence (American Urological Association Symptom Index) and 2 measures assessing both urinary and fecal incontinence (Pelvic Floor Distress Inventory – Short Form, Pelvic Floor Impact Questionnaire – Short Form). The Task Force also recommended two measures of urinary incontinence that demonstrated strong psychometric properties, but had not yet been evaluated in the cancer population (Incontinence Quality of Life Questionnaire, International Consultation on

Incontinence Questionnaire – Short Form). The Task Force was unable to recommend any measures that solely addressed fecal incontinence.

Conclusions—Five of the 13 outcome measures assessing urinary incontinence and two of the 13 measures assessing both urinary and fecal incontinence demonstrated satisfactory psychometric properties and application to the urogenital cancer population and are thereby recommended for use by the Task Force.

INTRODUCTION

Research has indicated that individuals with urogenital and colorectal cancers are more likely to experience urinary and/or fecal incontinence as a result of their cancer or of the treatment for their disease.^{1, 2, 3} Dysfunction in any of these areas can have significant impact on quality of life including higher levels of depression and anxiety, diminished enjoyment of sexual activity, as well as a significant economic burden in terms of supplies for symptom management.^{4, 5, 6} Assessment of the presence and severity of urinary and fecal incontinence is important for medical professionals to be able to thoroughly gauge disease impact.

Urinary incontinence (UI) is defined as any involuntary loss of urine. This condition includes leaking with a strong sense of urgency (urge UI), leaking with activities that cause increased intra-abdominal pressure such as changing positions, coughing, or sneezing (stress UI), mixed urgency and stress symptoms (mixed UI), nighttime urinary incontinence (nocturnal enuresis), post-micturition dribble, and continuous urinary leakage. In the general population, UI is experienced by over 50% of women and nearly 14% of men, with mixed and stress UI having a higher prevalence than urge UI.^{7, 8} In a study of 347 patients with suspected gynecologic malignancy, more than 50% reported UI with 19% reporting those symptoms as moderate-to-severe.⁹

Fecal incontinence (FI) is defined as any involuntary loss of fecal material. Risk of developing FI increases with age¹⁰ with 11–15% of community-dwelling adults reporting some degree of fecal leakage.¹¹ These numbers more than double in the colorectal cancer population.¹⁰ In a study of individuals with colorectal cancer who underwent resection surgery, over 40% reported liquid stool incontinence and 10% reported solid stool incontinence.²

The American Physical Therapy Association's (APTA) Evaluation Database to Guide Effectiveness (EDGE) Task Force was created to generate a list of quality outcome measures that are specific to different patient populations with the goal of increasing the implementation of evidence-based practice across the profession. The Oncology Section's EDGE Task Force has reviewed the literature on breast cancer outcomes including scapular and glenohumeral impairments, pain, lymphedema, and fatigue, and they have more recently expanded the evaluation of outcome measures to other types of cancer including urogenital and colorectal cancers. Although a variety of outcome measures have been used to assess urinary and fecal incontinence, no recommendations exist for psychometrically strong outcome measures covering these domains and their use within the cancer population. The primary objectives of this review were to identify outcome measures for assessing urinary

and fecal incontinence, and to evaluate their psychometric properties and applicability to the cancer population.

METHODS

To generate an initial list of outcome measures, the authors systematically searched the literature for outcome measures that assessed urinary and/or fecal incontinence and sexual dysfunction. The titles, abstracts, and methods section of each article were reviewed to identify outcome measures that were used to assess fecal or urinary incontinence or sexual dysfunction in persons diagnosed with cancer. When indicated, full articles were obtained for further review. Articles were included for consideration if the text was available in English and if it was related to urinary, fecal incontinence, or sexual dysfunction. Additionally, articles related to sexual dysfunction, while included in the original search of the literature, were excluded from this manuscript and will be published in a future manuscript (Alappattu et al, *in review*). Thus, only articles related to fecal or urinary incontinence were included in this manuscript. The publication dates were limited to January 1, 1995 to August 2015. The primary search was conducted in August 2015 in CINAHL, Medline, and PsycInfo. The search terms used for this study are listed in Table 1.

Each outcome measure was independently reviewed by two of the five members of the Task Force (MA, SH, AH, AJ, AR) using the Cancer EDGE Task Force Outcome Measure Rating Form (see Figure 1). This form details information about psychometric properties including reliability, validity, minimal detectable change (MDC), and minimal clinically important difference (MCID) as available. Clinical utility was also addressed and included the following: availability of the measure, length of the questionnaire, cost, time required to complete, and scoring and interpretation. As a part of the assessment, each reviewer ranked the outcome measure using the Cancer EDGE Task Force Rating Scale described in Table 2. Any discrepancies between the reviewers were discussed and a consensus was reached for the ratings and recommendations. The PRISMA diagram (Figure 1) illustrates the literature search and article selection process.

RESULTS

A comprehensive review of the literature yielded 13 outcome measures that assessed urinary and/or fecal incontinence (Figure 1). Of these measures, one measure of UI (American Urological Association Symptom Index) and two measures of combination urinary and fecal incontinence (Pelvic Floor Distress Inventory – Short Form, Pelvic Floor Impact Questionnaire – Short Form) received the highest rating (4) and were highly recommended for clinical use (Table 3). Two additional measures of UI earned the second highest rating (3): Incontinence Quality of Life Questionnaire and the International Consultation on Incontinence Questionnaire – Short Form. Although these measures have not yet been validated in the cancer population, their psychometric properties warrant our recommendation for use. Eight outcome measures were unable to be recommended at this time due to weak supporting evidence.

DISCUSSION

The purposes of this review were to systematically identify and analyze outcome measures for assessing urinary and fecal incontinence in the urogenital and colorectal cancer populations and to provide recommendations for their use in a clinical or research setting. Three measures received the highest possible rating for urinary incontinence and were highly recommended by the Task Force. Two other urinary incontinence measures recommended by the Task Force, but not highly recommended because they had not been utilized in the cancer population. These urinary incontinence measures are described below.

Urinary Incontinence Measures

American Urological Association Symptom Index (AUA-SI)

EDGE Rating: 4 (Highly Recommended): The AUA-SI assesses urinary urgency, frequency, and voiding symptoms. Also known as the International Prostate Symptom Score (I-PSS), the measure was originally developed and validated for patients with benign prostatic hyperplasia and used in research with individuals who have undergone prostatectomy, but has also been validated for assessment of lower urinary tract symptoms (LUTS) in women.¹² The AUA-SI is a 7-item self-report measure using a 5-point Likert response scale. Scores range from 0–35 with higher scores indicating greater severity of symptoms (Less than 8: mild symptoms, 8–19: moderate symptoms, 19+: severe symptoms). The measure demonstrates high internal consistency (Cronbach's $\alpha = 0.86$) and high test-retest reliability ($r = 0.92$). Spearman's correlation for stress, urge, and mixed incontinence was 0.790, 0.802, and 0.830, respectively ($P = 0.0001$).¹² Additionally, subjects' global ratings of the magnitude of their urinary symptoms showed a high correlation with AUA-SI scores.¹³ Finally, although no MCID has been established, the AUA-SI is sensitive to change as subjects who reported "slight improvement" had a mean decrease in AUA-SI scores by 3.1 points.¹⁴ This measure is brief, readily available online, and simple to administer, making it an effective tool to assess urinary symptoms in the cancer population.

Incontinence Quality of Life questionnaire (IQOL)

EDGE Rating: 3 (Recommended): The IQOL is a 22-item quality of life questionnaire with subscales to assess behavior, psychosocial impact, and social embarrassment relating to UI in both women and men. Each of the 22 items is scored 1–5 using a Likert scale with 1 being "extremely" and 5 being "not at all" with higher scores corresponding to higher quality of life. Subscale scores are calculated to form a total score. The IQOL has excellent internal consistency for both the summary score (Cronbach's $\alpha = 0.95$) and each subscale (Cronbach's $\alpha = 0.87$ for the behavior subscale, 0.93 for the psychosocial impact subscale, and 0.91 for the social embarrassment subscale).¹⁵ Construct validity for the IQOL included correlations with subscales of the SF-36 Health Survey ranging from 0.15 to 0.48 and correlations with the Psychological General Well-Being summary and subscale scores ranging from 0.18 to 0.48 with all correlations being significant except "bodily pain".¹⁵ These correlations, while significant, are low. One potential reason for this may be that the SF-36 and Psychological General Well-Being are measures related to general physical and mental functioning, while the IQOL is specific to the impact of UI on psychosocial impact, behavior, and embarrassment. The MCID for the IQOL total score is reported as 6.3 points

for within treatment changes and 2.5 points for between treatment changes.¹⁶ According to Bushnell et al,¹⁷ there were potential ceiling and floor effects noted for five of the items on the IQOL. The IQOL is available in a variety of languages and demonstrates strong psychometric properties and is therefore recommended for clinical use. The one limitation of this measure is that it has not yet been validated in individuals with cancer.

International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF)

EDGE Rating: 3 (Recommended): The ICIQ-SF is a 5-item self-report questionnaire that assesses the frequency and amount of UI as well as the quality of life impact. The measure is available in over 30 languages and has been validated for both males and females with overactive bladder, nocturia, or primary stress urinary incontinence, being treated either surgically or conservatively.²⁰ Two demographic items are not scored. The remaining three items are uniquely scored to generate a total score ranging from 0–21 with greater values indicating increased severity of incontinence impact. Previously published work indicates that a score between 1–5 is slight impact, 6–12 is moderate impact, 13–18 is severe impact, and 19–21 is very severe impact.¹⁸ The frequency of incontinence question is scored 0–5; usual amount of incontinence question is scored 0 for “none”, 2 for “a small amount”, 4 for “a moderate amount” and 6 for “a large amount”; and the interference with daily life question is scored 0–10, with 0 being “not at all” and 10 being “a great deal”. The ICIQ-SF demonstrates high internal consistency (Cronbach’s $\alpha = 0.92$), as well as adequate test-retest reliability for the frequency (kappa = 0.73) and amount domains (kappa = 0.67).¹⁹ The questionnaire demonstrated sensitivity to change with both surgical and conservative management²⁰ and the MCID was found to be –5 at 12 months and –4 at 24 months.²¹ Overall, the ICIQ-SF demonstrates strong psychometric properties, is short and simple to understand, is easy to score, and provides useful data on both severity of incontinence and quality of life changes due to incontinence. Similar to the IQOL, one limitation of this outcome measure is that it has not been applied in research to individuals with cancer.

With regards to measures that assessed both urinary and fecal incontinence, two measures received the highest possible rating (4) and were therefore highly recommended by the Task Force and are described below.

Urinary and Fecal Incontinence Measures

Pelvic Floor Distress Inventory – Short Form (PFDI-20)

EDGE Rating: 4 (Highly Recommended): The PFDI-20 contains 20 questions that assess the impact of pelvic floor disorders on the health-related quality of life (HRQoL) in women including urinary, prolapse, and gastrointestinal dysfunction.²² The measure is both a symptom and bother inventory and is answered on a 4-point Likert scale.²⁵ The PFDI-20 evaluates three domains of distress: pelvic organ prolapse distress inventory 6 (POPDI-6), colorectal anal distress inventory 8 (CRADI-8), and urinary distress inventory 6 (UDI-6). All three domains and the total score demonstrate high internal consistency with total score (Cronbach’s $\alpha = 0.908$). POPDI-6 $\alpha = 0.942$, UDI-6 $\alpha = 0.965$, and CRADI-8 $\alpha = 0.964$.²⁴ The PFDI-20 also demonstrates excellent test-retest reliability (ICC = 0.93).²⁵ The mean of each domain is multiplied by 25 to obtain a score ranging from 0 to 100. A total summary

score (range 0–300) is calculated by adding the three domain scores with higher scores indicating a greater impact on HRQoL. Barber et al²² established a long term MCID as a change in 45 or more points on the summary scale. The PFDI-20 has been validated in women with pelvic floor distress, and the measure has been used in studies in women with endometrial cancer.²⁶

Pelvic Floor Impact Questionnaire – Short Form (PFIQ-7)

EDGE Rating: 4 (Highly Recommended): The PFIQ-7 is designed to assess, via self-report, the extent to which bladder, bowel, and vaginal symptoms affect women's activities, relationships, and feelings.²³ Each of the seven questions asks individuals to rate their level of interference in three areas (satisfaction, impact, and worry) on a 4-point Likert scale ranging from 0 = "not at all" to 3 = "quite a bit".²³ Scoring is determined by estimating the mean value for each subscale and then multiplied by 100 and divided by 3 to obtain the scale score (range 0–100). Each subscale score is added to form a PFIQ-7 summary score ranging from 0–300 with higher scores indicating worse health status. The PFIQ-7 demonstrates high internal consistency for the total score (Cronbach's $\alpha = 0.83$) as well as the prolapse symptoms domain (POPIQ-7 $\alpha = 0.76$), urinary symptoms domain (UIQ-7 $\alpha = 0.80$), and the colorectal symptoms domain (CRAIQ-7 $\alpha = 0.73$).²⁴ Similar to the PFDI-20, the measure has been validated in women with pelvic floor disorders, and used in studies in women with endometrial cancer.²⁶ Due to its strong psychometric properties and ease of administration and completion, the PFIQ-7 was highly recommended for clinical use by the Task Force.

Fecal Incontinence Measures

The reviewers were unable to highly recommend or recommend a measure solely addressing fecal incontinence. Two measures, the American Society of Colon and Rectal Surgeons Fecal Incontinence Questionnaire and the Fecal Incontinence Severity Index, were both given a rating of 2 due to insufficient psychometric support; however, the ASCRS Fecal Incontinence Questionnaire has been used in the cancer population, earning this measure a 2A rating.

Overall, the reviewers were unable to recommend 8 of the reviewed outcome measures at this time. Three of these measures, the Urogenital Atrophy Questionnaire, Incontinence Impact Questionnaire, and American Social of Colon and Rectal Surgeons Fecal Incontinence Questionnaire have all been used in the cancer population, however the psychometric properties of these measures are inadequate at present. Two measures, the 24-hour pad test and Fecal Incontinence Severity Index, also had weaker psychometrics, larger response burdens, and were also general measures that had not been applied to the cancer population, which limited their clinical utility. Finally, five measures (1-hour pad test, Pelvic Floor Distress Inventory - Long Form, Pelvic Floor Impact Questionnaire - Long Form, Radiumhummet Scale of Disease Specific Symptom Assessment - Prostate Cancer, and Cleveland Clinic Fecal Incontinence Score) were given a score of 1 due to high response and scoring burdens, inadequate psychometrics, and no evidence of use in the cancer population.

SUMMARY

Our results demonstrate a need for increased scrutiny to evaluate the psychometric properties of existing outcome measures for incontinence. A significant limitation to these results is that there were no recommended measures of FI that are applicable to men. This is particularly important since colorectal cancers have a higher incidence in men.²⁷ The limited amount of high quality studies validating the use of incontinence outcome measures in the cancer population begs the question as to whether urinary and fecal incontinence are inherently different in individuals with cancer. For example, is incontinence different for an individual who experiences incontinence after childbirth or a urological or gynecological surgery compared to someone who developed incontinence due to treatment for cancer? Future work in this area should address this question to determine if patients with cancer who have urinary or fecal incontinence require measures that are specific to patients with cancer rather than those that have been validated in the non-cancer population. Future research in this area may help to clarify the clinical utility of these outcome tools and may provide information to strengthen the evidence of some of these measures.

When interpreting the Task Force's recommendations, several key considerations exist. The primary limitation is the time component between the literature search and the publication of this paper. New studies may have been published after the literature search was conducted which may provide evidence to support measures that could not be recommended at this time. Future expansions on the clinical utility and strength of outcome measures for incontinence will include this increased body of evidence as well as evaluating the use of these measures within the cancer population. The literature search was restricted to journals and articles in English. This may have limited the number of measures reviewed that could have been available in journals in other languages. The recommendations of the Task Force are intended to serve as a guide to increase evidence-informed practice in selection of outcome measures. Practitioners are encouraged to consult the overall recommendations as well as the individual information for each outcome measure and any new literature in order to select appropriate measures of urinary and fecal incontinence.

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Figure 1.
PRISMA flow diagram

Table 1

Search terms for initial review of literature

Search Strategy	Cancer	Incontinence	Outcome Measures
Search Terms & Strings	“Neoplasms+”, “Prostatic Neoplasms+”, “Testicular Neoplasms+”, “Colorectal Neoplasms+”, “Breast Neoplasms+”, “Bladder Neoplasms”, “Urethral Neoplasms”, “Carcinoma, Renal Cell+”, “Vulvar Neoplasms”, “Vaginal Neoplasms”, “Ovarian Neoplasms+”, “Uterine Neoplasms+”, “Urinary Bladder Neoplasms”, “Benign Neoplasms”, “Endocrine Neoplasms”, “Leukemias”, “Nervous System Neoplasms+”, “Terminal Cancer”, cancer, neoplasm, carcinoma, leukemia, lymphoma, melanoma, sarcoma	“Incontinence+”, “Urinary Incontinence+”, “Fecal Incontinence”, incontinence, urinary dysfunction, urinary function, fecal dysfunction, fecal function	“Reproducibility of Results+”, “Reliability and Validity+”, “Psychometrics”, “Data Collection”, “Focus Groups”, “Interviews+”, “Self Report”, “Surveys”, “Clinical Assessment Tools+”, “Research Instruments+”, “Factor Analysis, Statistical”, “Geriatric Assessment”, “Health Surveys”, “Health Status Indicators+”, “Health Care Surveys”, “Interviews as Topic”, “Questionnaires+”, “Testing +”, “Measurement+”, “Statistical Analysis+”, “Statistical Reliability”, “Consistency (Measurement)”, “Interrater Reliability”, “Test Reliability”, “Test Validity”, reliability, valid, psychometric, clinimetric, questionnaire, survey, index, indices, scale, assess, evaluate, measure, inventor, test

Table 2

Cancer EDGE Rating Scale

4	Highly Recommend	Highly recommended; the outcome has good psychometric properties and good clinical utility; the measure has been used in research on individuals with or post cancer.
3	Recommend	Recommended; the outcome measure has good psychometric properties and good clinical utility; no published evidence that the measure has been applied to research on individuals with or post cancer.
2A	Unable to Recommend at this time	Unable to recommend at this time; there is insufficient information to support a recommendation of this outcome measure; the measure has been used in research on individuals with or post cancer.
2B	Unable to Recommend at this time	Unable to recommend at this time; there is insufficient information to support a recommendation of this outcome measure; no published evidence that the measure has been applied to research on individuals with or post cancer.
1	Do Not Recommend	Poor psychometrics &/or poor clinical utility (time, equipment, cost, etc.).

Clinical Usefulness of Incontinence Outcomes Highly Recommended (4) and Recommended (3) Measures

Table 3

Measure	Equipment Needed	Cost	Ease of Use	Scoring/Interpretation	Normative Data	Validated in Cancer	Gender(s)
Urinary Incontinence – Highly Recommended							
American Urological Association Symptom Index (AUA-SI)	Paper pencil &	Free	Easy	Easy	Yes	Yes	Both
Urinary Incontinence – Recommended							
Incontinence Quality of Life Questionnaire (IQOL)	Paper pencil &	Free	Easy	Easy	Yes	No	Both
International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF)	Paper pencil &	Free *	Easy	Moderate	Yes	No	Both
Urinary and Fecal Incontinence – Highly Recommended							
Pelvic Floor Distress Inventory – Short Form (PFDI-20)	Paper pencil &	Free *	Easy	Easy	Yes	Yes	Women
Pelvic Floor Impact Questionnaire – Short Form (PFIQ-7)	Paper pencil &	Free *	Easy	Moderate	Yes	Yes	Women

Abbreviations:

* Free with license &/or copyright agreement.

Table 4

Results of Task Force literature review by rating

Rating	Urinary Incontinence	Urinary & Fecal Incontinence	Fecal Incontinence
4 – Highly recommend	<ul style="list-style-type: none"> American Urological Association Symptom Index 	<ul style="list-style-type: none"> Pelvic Floor Distress Inventory-Short Form Pelvic Floor Impact Questionnaire-Short Form 	N/A
3 – Recommend	<ul style="list-style-type: none"> Incontinence Quality of Life Questionnaire International Consultation on Incontinence Questionnaire - Short Form 	N/A	N/A
2A – Unable to recommend at this time	<ul style="list-style-type: none"> Urogenital Atrophy Questionnaire Incontinence Impact Questionnaire 	N/A	<ul style="list-style-type: none"> American Society of Colon and Rectal Surgeons Fecal Incontinence Questionnaire
2B – Unable to recommend at this time	<ul style="list-style-type: none"> 24 hour pad test 	N/A	<ul style="list-style-type: none"> Fecal Incontinence Severity Index
1 – Do not recommend	<ul style="list-style-type: none"> 1 hour pad test 	<ul style="list-style-type: none"> Radiumhummet Scale of Disease Specific Symptoms Assessment -Prostate Cancer 	<ul style="list-style-type: none"> Cleveland Clinic Fecal Incontinence Score